REMARKS

By the above amendments, claims 1-4, 12, 20, and 21 are revised and new claim 22 is added to place this application in immediate condition for allowance. Currently, claims 1-22 are before the Examiner for consideration on their merits.

In response to the issues raised under the 35 U.S.C. § 112, second paragraph rejection, claim 1 is revised to remove "likely to be present" and claims 2-4 and 12 are revised to clarify the alternative language of claim 2 and the markush groupings. Claim 14 is revised to remove reference to "hand." Claim 20 is revised to address the concern regarding a lack of antecedent basis. In addition, new claim 22 is added to cover the embodiment wherein the wort is both fermented and matured. Claim 21 is revised to clarify the weight percentage of the fermented wort.

Applicants also submit that the language of claim 1, i.e., adsorbing at least part of the mycotoxins" is not indefinite. The use of "at least part of" means that not all of the mycotoxins have to be adsorbed and there is nothing indefinite about this language. Moreover, using the word "part" to describe a portion of the mycotoxins is also not indefinite, when one of skill in the art reads the claim in light of the specification. The specification is also clear in this regard, see page 7, lines 7-13, wherein the inventive process makes it possible to remove a significant degree of the mycotoxins present in the dietary products. Thus, it is submitted that this aspect of claim 1 is not indefinite.

The specification has also been revised to replace the use of "absorb" or a variation thereof with the proper term of "adsorb." This does not introduce new matter since it is clear from the original specification that the mechanism for collecting the

mycotoxins was for them is the physical immobilization of the mycotoxins on the surfaces of the fibers or an adsorption mechanism.

In light of the changes to the claims, all issues raised under 35 U.S.C. § 112, second paragraph, have been addressed and this rejection should be withdrawn.

Turning now to the prior art rejection, claims 1-15 stand rejected under 35 U.S.C. § 103(a) based on EP 0124891 to Yoshihide et al. (Yoshihide) when modified by United States Patent No. 4,770,880 to Sasaki et al. (Sasaki), and taking into account the teachings of Coffee Review 2000 to Davids, Toxicology Letters 2001 to Huwig et al. (Huwig) and Mutation Research 2004 to Kada et al. (Kada).

Claims 1-21 are also rejected on the combination of Yoshihide and Sasaki when modified by the Boeira et al. (Boeira) article from J. Appld. Micro 2000.

In rejecting claim 1, the Examiner characterizes Yoshihide to teach the invention but for removal of the fiber by filtration. The position that the fibers inherently "absorb" mycotoxins is allegedly supported by reference to Kada and Huwig. Davids is cited to allege that Yoshihide inherently meets the pH limitation of claim 10. In response to this failure of Yoshihide to teach removing the fibers by filtration, the Examiner cites Sasaki to contend that it would be obvious to employ such a step in Yoshihide.

It is submitted that the Examiner has either failed to establish a *prima facie* case of obviousness against the claims or that any such allegation is effectively rebutted by the comparative evidence found in the specification. This traverse is outlined below under the heading of the INVENTION and the applied prior art.

INVENTION

The invention relates to a biological process that has essentially two steps. The first step is the adsorbing of at least a part of the mycotoxins which are present in a dietary medium to be decontaminated. The adsorbing is accomplished by bringing the medium into contact with micronized insoluble plant fibers. Then, the fibers containing the adsorbed mycotoxins are removed.

Important to note in the invention described above is that the removal process involves adsorbing. Adsorption is a process that occurs when a gas or liquid solute, mycotoxins in the instant case, accumulates on the surface of a solid, micronized insoluble fiber in the instant case, to form a molecular or atomic film or adsorbate. This phenomenon is clearly seen in Example 2, wherein one can observe that adsorption follows the law of diminishing returns and correlates with the Freundlich model.

This is different from absorption, wherein a substance diffuses into a liquid or solution to form a solution.

It is also important to note that the plant fiber is not any fiber but a micronized insoluble fiber. Micronization is the process of reducing the average diameter of a solid material's particle. Typically, the term micronization is used when the particles that are produced are on the order of a few microns in diameter.

Moreover, the invention, see page 7, line 28 to page 8, line 2, provides a particularly effective and simple solution for removing mycotoxins from liquid dietary

products. The inventive process can be implemented at a low cost and generally without any major modifications of the manufacturing process presently employed.

It is especially effective in the brewing process wherein it exhibits another advantage of facilitating the filtration step and improving the stability of the foam. This advantage is evident when considering claim 17 that deals with the brewing process and at least one step of mashing and at least one step of fermenting a wort. The inventive decontamination step is combined with these steps, either simultaneously with the mashing step and after the step of fermenting and/or maturing. Alternatively, the decontamination step takes place after the fermenting and/or maturing steps but not with the mashing step.

The specification also demonstrates the unexpectedly high enhancement of the amount of the adsorbed mycotoxins since a comparison is made using insoluble plant fibers which are not micronized. Example 1, Table III of the specification demonstrates that the percentage of mycotoxins adsorbed onto insoluble plant fiber is enhanced by a factor or 2 when the fibers are micronized. This means that, if an objective is to reach a decontamination yield of about 60%, one can deduce on the curve that 1% of micronized insoluble plant fiber are needed to reach this yield, (black squares), this amount being about 8% if non-micronized insoluble plant fibers are used (black lozenges, or 8 times more than with micronized fibers. This evidence will be discussed again below when arguing against the rejection.

REJECTIONS

In the first rejection, the Examiner interprets Yoshihide to teach the invention but for the removal of fibers containing the mycotoxins. It is respectfully submitted that the Examiner's interpretation of the teachings of Yoshihide is not correct and this reference does not teach the adsorption process of claim 1.

Yoshihide teaches an antimutagenic agent and method of inactivating the mutagenicity of food. It should be initially noted that the Examiner incorrectly alleges that Yoshihide "teach a method to remove mycotoxins," see line 3 of page 5 of the Detailed Action. Yoshihide's process inactivates the mutagenic agent; there is no removal whatsoever.

The antimutagenic agent of Yoshihide is made from wheat germ, barley malt, soybean, powders thereof, rice bran, and extracted fractions thereof, see page 4, lines 6-10. Important to note here is that wheat germ corresponds to a very particular part of wheat berries, which does not contain any fibers, and accordingly no insoluble fibers. Wheat germ, as is well known, contains a high amount of lipids and proteins and has important enzymatic activity.

Soybeans and barley malt are also known to contain only a weak fraction of fibers, which rice bran contains fibers in a significant amount.

Yoshihide teaches two distinct kinds of products. A first one is a raw material mixture having a very weak fraction of which that contains fibers. A second one is the "active" preparation, which is much more effective than the raw material mixture. The active preparation is prepared from the raw materials, see for example, page 4, lines 15-21, the description of the figures and examples of Yoshihide. The active preparation

is used to decrease or to inactivate the mutagenicity of foods and beverages such as coffee, tea, and bourbon whiskey.

According to Yoshihide, it is possible for the active preparation to be constituted only by a soluble fraction of the raw material. After the raw material has been put into solution, there is a centrifugation and a step of filtration to eliminate the insoluble fraction of the raw material, and the remaining being the soluble fraction, which is the active preparation, see Example 2 beginning on page 16. As explained on page 17, lines 5-7, the dry particles of extracts were dissolved or suspended in distilled water for use in the experiment.

The important point being made here is that Yoshihide teaches that the active preparation of Yoshihide is the **soluble fraction** of the raw material, not the **insoluble fraction**. This interpretation is supported when considering that the centrifugation pellet of Yoshihide would contain insoluble fractions but the filtrate, which is what is used as the active preparation contains only soluble fractions. Thus, the only reasonable interpretation of the teachings of Yoshihide is that the soluble fraction has the property of inactivating the mutagenic agents.

Looking at claim 1 again, the process requires that medium is contacted with **micronized insoluble plant fibers**, which is not the case in Yoshihide.

Another distinction is that claim 1 requires micronized insoluble plant fibers. In Yoshihide, there is no mention of the importance of the size of the powders. While it is true that Yoshihide teaches powders, these powders are obtained by lyophilization of the filtrate containing the soluble fractions. However, the size of this powder is of no

importance since the powder is then resolubilized at the time of use, see the examples of Yoshihide.

Yet another distinction between the invention and Yoshihide is the claimed step of adsorbing of the mycotoxins onto the insoluble plant fibers. It is submitted that this mechanism is not present in Yoshihide, and it cannot be contended that Yoshihide teaches this step, either expressly or inherently.

When a soluble fraction is used for inactivation, the mechanism by which inactivation of the mutagenic agent can not be an adsorption phenomenon since the adsorption is the result of a physical interaction between a solid and a liquid.

The technical problem forming the basis of the invention of Yoshihide is finding a solution that will either decrease or suppress the mutagenicity of mutagenic agents susceptible to be present in a food product such as coffee. Yoshihide solves this problem by adding an active preparation to the food product. The question here is what is the mechanism by which the decrease or suppression of the mutagenic agents in the treated food product. Applicants submit that it is not by adsorption, which is required by the claims. If the mechanism of action of the active preparation were adsorption, it would be obligatory to eliminate the mutagenic agent. Otherwise, the mutagenic agent would sorb back to the food product since adsorption is a reversible phenomenon. If such sorption would occur during digestion of the food product by the organism, there is then a risk that the mutagenic agent regains its mutagenicity, which would not be acceptable.

It is clear that Yoshihide does not mention whatsoever that the active preparation has to be removed from the food product before its consumption. Here, it should be noted that removal by filtration of the soluble fraction employed by Yoshihide is not possible.

Another point to note is that Yoshihide indicates that it is possible to use the antimutagenic preparations simultaneously with hydrogen peroxide to enhance the inactivation. It is well known in the art that hydrogen peroxide is an oxidant that has a powerful action of chemical degradation and hydrogen peroxide does not act by adsorption.

The only reasonable conclusion to reach here is that Yoshihide does not teach the adsorbing step of claim 1 as is alleged in the rejection. With this conclusion, the question remains as to whether the secondary references could be relied upon by the Examiner to make us for this failing.

Sasaki does not teach the invention for the simple fact that micronized insoluble fibers are not taught or suggested. Sasaki relates to a process for the preparation of a product capable of adsorbing mutagens. This process consists in separating fibers from a vegetable, boiling the fibers and then washing and dewatering fibers. The product that is obtained from this process is in a dry state and in a particulate form, especially in the form of powders, granules, agglomerates of powders, and/or granules, see col. 2, line 12+. There is clearly no micronizing treatment in Sasaki. At the end of the process of Sasaki, the resulting product is incorporated in food as a food supplement and the food is then ingested, see col. 2, lines 12-51, and col. 7, lines 38-51.

While the Examiner relies on Sasaki to allege removal of the mutagens, no such removal is done. As stated above, Sasaki teaches a food supplement that is to be added to food when ingested.

It is also argued that Sasaki and Yoshihide are fundamentally different processes and are not properly combined. In fact, it is not totally clear as to how Sasaki is used in the rejection. The Examiner admits that Yoshihide does not teach removal of the fibers having the adsorbed mycotoxins. The Examiner then cites Sasaki as teaching the removal of mutagens using plant fiber. This assumption is wrong since Sasaki teaches that the food supplement is added to food for ingesting. Thus, the basis for relying on Sasaki to modify Yoshihide is not understood and regardless, the combination is improper given the divergent nature of the approaches of these two references.

Kada does not supply the deficiencies in Yoshihide. Kada's teachings are similar to Sasaki in reporting a study about the ability of fibers of many kinds of vegetables to inactivate the pyrolysate mutagens, derived from amino acids such as tryptophane. However, pyrolysate mutagens are far removed from mycotoxins from a chemical standpoint.

In Kada, the fibers are pretreated according to a process consisting of mashing of the crude material through a disposal filter with running water, boiling the residue to remove starch and other water-soluble materials, and then extracting and dehydrating with 99% ethanol. There is no micronization in Kada, nor are the steps of claim 1 taught.

Davids is cited only to support the allegation that the claimed pH level is obvious. Regardless of the obviousness of this issue, Davids is unrelated to Yoshihide and cannot form the basis for a new rejection.

Huwig also fails to supply the missing parts of Yoshihide. Huwig relates to the detoxification of animal feed using adsorbents. The historical approach to this problem is discussed as are different strategies for solving this decontamination problem. One particular strategy is the addition of adsorbents to mycotoxins-contaminated diets with the hope of being effective in the gastro-intestinal tract.

Two important things are lacking in Huwig. First, there is no discussion of the micronization of insoluble plant fibers. Second, there is no talk of removing the fibers with the adsorbed mycotoxins. The strategy pointed out above is consistent with the approach of Sasaki in that the treated food is ingested to produce the effect against mycotoxins.

The article by Boeira also does not provide a basis to make a further rejection of the claims. Boeira only recognizes the effect of *Fusarium* mycotoxins on growing of brewing yeast. Thus, even if Boeria were combined with the other references, the failings in Yoshihide and the other references are not remedied.

Applicants also contend that the comparative evidence in the specification further supports the patentability of the invention. Example 9 beginning on page 34 of the application compares micronized and non-micronized fibers for their effect on adsorption of AFB1. This evidence shows that the micronized fibers provide vastly superior results and these results are unexpected in the art. Thus, even if the Examiner

were to allege that the prior art establishes a *prima facie* case of obviousness against the claims, this case is rebutted by the showing in the specification.

SUMMARY

In summary, Applicants contend that neither Yoshihide nor the other cited prior art teaches the adsorbing and removing steps of claim 1, and this claim is patentably distinct from the applied prior art. Even if the Examiner were to continue to assert obviousness, the comparative results in the specification demonstrate unexpected results when using the micronized insoluble plant fibers.

Accordingly, the Examiner is requested to examine this application in light of this amendment and pass all pending claims onto issuance.

If the Examiner believes that an interview would be helpful in expediting the allowance of this application, the Examiner is requested to telephone the undersigned at 202-835-1753.

The above constitutes a complete response to all issues raised in the Office Action dated May 3, 2007.

Again, reconsideration and allowance of this application is respectfully requested.

A check in the amount of $25.00 is enclosed to cover the submission of an extra dependent claim.

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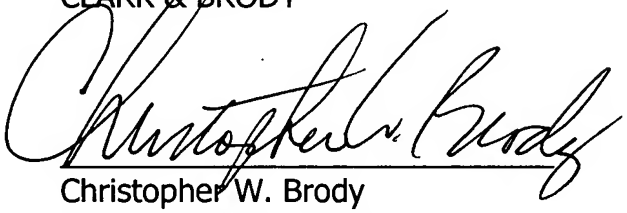
Respectfully submitted,
CLARK & BRODY



Christopher W. Brody
Registration No. 33,613

Customer No. 22902
1090 Vermont Ave., N.W., Suite 250
Washington DC 20005
Telephone: 202-835-1111
Facsimile: 202-835-1755

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